SUBJECT:	Fermilab Assessment Manual – Chapter 4 Independent QA Assessment Procedure – Form 2	NUMBER:	3902.1004 FORM 2
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001.3
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	06/20/2011

Assessment Number & Title: 11-IA-QA-011 ES&H Measuring & Test Equipment (M&TE) Version: 1.0

Date(s) of Assessment: 08/01/11 - 08/19/11

Performing Organization: Office of Quality & Best Practices (OQBP)

Assessed Organization(s): Environment, Safety, and Health (ES&H) including:

- Radiation Protection Group Instrumentation Team
- Radiation Protection Group Dosimetry Program Manager

Assessment Activities & Scope:

Implementation and effectiveness of controls for (M&TE) relative to the requirements of Integrated Quality Assurance (IQA) were examined via interview, observation, and review of documents and records. These controls were examined across the ES&H organization listed in the "Assessed Organization(s)" section of this report.

Scope Limitations:

Although other groups within the Section use M&TE, at the request of ES&H management the Radiation Protection Group – Instrumentation Team and Dosimetry Program Manager were the only ES&H organizational areas within the scope of this assessment. This decision by the ES&H management was based on a risk/benefit review of the M&TE in the ES&H Section.

Activities Reviewed Within this Assessment:

- Management of the Dosimetry Badge Maintenance Program
- Management of the ES&H M&TE program including Calibration, Maintenance and Repair
- Calibration of the M&TE in the above programs

Description of the Implementation & Effectiveness of Observed Activities:

Measuring and Test Equipment:

The M&TE requirements of IQA chapters five and eight are met and effectively implemented within the ES&H Radiation Protection Group, Instrumentation Team. These requirements were not assessed in the Safety/Industrial Hygiene, Environmental Protection, and Fermilab Medical Office Groups.

The ES&H Radiation Protection Instrumentation Team is responsible for the calibration, maintenance, accountability and repair of the laboratory's ES&H instrumentation. The calibration and maintenance program implemented by this team was assessed. The assessment team observed a complete list of all equipment that have historically been calibrated as part of the program (File01), a list of all equipment used to perform calibration (File02), and a list of all equipment due for calibration during the month of July, 2011 (File03). Of the equipment scheduled for calibration in July, 7.7% (14/181) of the equipment was past due for calibration. This is a large improvement over the 2009 "As-is" assessment finding, that for February 2009, "50 – 60% of the instruments are past due for calibration".

Controlled calibration worksheets were observed for 6 types of M&TE. These worksheets contain detailed

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inspection, test, calibration and maintenance instructions as well as tables to record results. Execution of the calibration procedures for a Ludlum 177-4 Frisker and a Bicron Surveyor 50 (File04) were observed, except for the "calibration source" measurements performed in Cave 3. In both cases a high degree of expertise was demonstrated by personnel performing the test, maintenance and calibration.

Two interviewees stated that they inform equipment users when they find a piece of M&TE out of calibration. An email notification and the IMAC Pre-Calibration Notification System Worksheet (File05) confirmed this. However, there was no evidence that the new notification system, RPIT Pre Calibration Notification System, was being actively used by the two interviewees to notify D/S/Cs that M&TE was found to be out of calibration tolerance.

Calibration status of equipment being used to inspect, maintain, test and calibrate other equipment was examined. Of the 11 pieces of equipment examined, 9 had calibration stickers that indicated they were within the current calibration interval. Two pieces of equipment, the Micronta #2 Hygrometer/Thermometer, located in cave 3 and the Associated Environmental Systems Environmental Chamber model 32-508, CSI 87201, located on the second floor, had no calibration stickers. Calibration certificates (File06) were examined for ten pieces of M&TE. All ten certificates stated that standards traceable to the National institute of Standards and technology (NIST) were used. Four of the five organizations issuing the certificates included accreditation information on the certificate. There was no evidence of accreditation information on the certificates issued by the fifth organization.

Approximately 9.5% (217/2272) of all the M&TE contained on the historical list of equipment is categorized as "lost" (File01). M&TE is categorized as lost after it has been past due for calibration for three consecutive months. It is possible that some of these M&TE are not really lost and that they are being used by the Division, Sections, and Centers (D/S/Cs) even though they are past due for calibration.

The ES&H Dosimetry Badge Maintenance program ensures that personal Dosimetry badges are calibrated and maintained. Biannual assessments of the program are performed by Department of Energy Laboratory Accreditation Program (DOELAP) independent assessment teams. Assessment reports dated 2/22/08 (File07) and 2/24/10 (File08) were observed. Both of these reports contained statements that all of the observations and concerns of the previous report had been implemented and verified.

Conclusions:

The ES&H Radiation Protection Group, Instrumentation Team, has effectively implemented an M&TE program that meets the requirements found in chapters five and eight of the IQA. The program includes providing maintenance and calibration services to Fermilab D/S/Cs as well as maintenance and calibration of their own M&TE. The Dosimetry Badge maintenance program is reviewed biannually by independent assessors with evidence that findings are resolved and verified. There were no findings of non-compliance found during the assessment, but possible areas for improvement are noted in the Observations and Recommendations section below.

Findings: None

Observations and Recommendations:

1. **Observation:** There were two instances of M&TE in use that did not have calibration stickers. **Recommendation:** Ensure M&TE used to calibrate, test, and maintain equipment contain required calibration stickers.

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2. **Observation:** Equipment is placed on the Lost Instrument List after it has been past due for calibration for 3 consecutive months. This equipment is categorized as "lost" even though the actual status of the equipment may be unknown. All D/S/Cs have equipment in the lost category.

Recommendation: A determination of the actual status of this equipment should be made. D/S/Cs should improve on delivering the M&TE that appears on the monthly due list to ES&H. This issue should be escalated to a level sufficient to cover all Fermilab D/S/Cs.

3. **Observation:** A Fluke 8842A Multi-meter, serial # 04542282 was observed in the Mobile Environmental Radiation Laboratory (MERL) truck. A calibration form was attached to the top of the instrument stating "FAILS NIST Cal" with the failures highlighted in red.

Recommendation: Consider identifying the equipment with a label, such as "Not Calibrated"

- 4. Observation: There was evidence that the newer version of the RPIT Pre Calibration Notification System was not being used to inform people that M&TE in their area was found to be out of calibration tolerance. Recommendation: Communicate to personnel performing calibration that the newer RPIT Pre Calibration Notification System should be used to inform people that M&TE in their area was found to be out of calibration tolerance.
- 5. **Observation:** Requirements for suppliers of calibration services to ES&H are not clearly defined. **Recommendation:** Consider defining and checking the requirements of suppliers of calibration services (such as whether accreditations are required) to ES&H.

Commendable Practices:

1. The Calibration Worksheets which combine test, calibration, and maintenance instructions along with areas to record the calibration results are a good method of integrating these two pieces of the calibration process in one place.

Names of Persons Interviewed:

Darrel Bancroft Butch Hartman Scott Hawke John Larson Sue McGimpsey

Documents Reviewed:

Fermilab ES&H Section Low Level Calibration Facility (LLCF) Operating Procedures Rev. 2 Fermilab Radiological Control Manual Rev. October 2010 Fermilab Mobile Environmental Radiation Laboratory Procedures Manual Rev. 001

(See also "Attachments" section below)

Standards, Regulations, and Other Program Requirements Applied:

The specific criteria applied to this assessment were:

1001 IQA section 5.4.2, Maintenance (relative to M&TE)

1001 IQA section 5.4.4, Calibration of Process Equipment

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1001 IQA section 8.5, Control of Measuring &Test Equipment

Describe or List Any Other Assessment Methods Used: None

Corrective Action Plans Issued: None

Assessors' Names (asterisk indicates team leader):

- Bakul Banerjee CD
- John Martzel* OQBP

Submitted by: John Martzel Date: 8/19/11

Distribution (Distribute to assessed organizations' management, OQBP head, and other interested parties):

Nancy Grossman

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Bob Grant

Ed Vokoun

Jed Heyes

Bakul Banerjee

Butch Hartman

Attachments:

File01 – Overall List of M&TE to be calibrated by ES&H

File02 – List of ES&H M&TE used to calibrate other equipment

File03 – List of equipment to be calibrated during July, 2011

File04 – Bicron Surveyor 50 Calibration Worksheet

File05 – IMAC Pre-Calibration Notification System Worksheet

File06 - Calibration Certificates

File07 – 2008 DOELAP Dosimetry Assessment Report

File08 – 2010 DOELAP Dosimetry Assessment Report